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Implementation, Prevalence, and Referral Rates of Patient-Reported Outcomes of Distress and Depression Screening in Oncology Care

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Master of Public Health Thesis

May 2021

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Abstract

Clinical depression and distress are prevalent in cancer patients and are often unrecognized by clinicians. However, patient-reported outcomes, or PROs, can facilitate provider assessment of oncology treatment plans by detecting depressive and distress symptoms early in a patient's cancer trajectory. Since PROs capture patients' subjective experience, they provide invaluable insight into patient satisfaction, quality of life, and mental health. In April 2019, leadership at Smilow Cancer Hospital at Yale New Haven Health implemented a new, electronic workflow that widely disseminated PHQ-9 and NCCN Distress questionnaires to patients seen in three Smilow Cancer Hospital Care Centers. The objective of this pilot study was to improve early detection of depression and distress in cancer patients through PROs. Prevalence of distress, depression, and self-harm was analyzed across age, sex, race, gender, time since diagnosis, and cancer center, and statistically significant differences were validated with a chi-square analysis. 18.6% of patients had positive distress and 5.3% had positive PHQ-9 Scores indicating depression. For those with depression, 1.67%, 1.69%, 0.92%, and 0.34% had mild, moderate, moderately severe, and severe depression, respectively. All patients were referred to appropriate interventions. Additionally, an unconditional logistic regression was performed to understand significant predictors of self-harm and suicidal ideation. 1.00% of patients suffered from suicidal ideation and self-harm. Moderately severe depression and severe depression were statistically significant predictors for self-harm. Moreover, this study recognized clinical distress and depression and provided interventions to these patients. Future implementation of PROs of distress and depression surveys in cancer patients should consider incorporating culturally sensitive questions, acknowledging language barriers, and making accommodations for patients with cognitive impairments.

Acknowledgements

I would like to thank my thesis advisors, Dr. Melinda Irwin and Dr. Xiaomei Ma, as well as Donna Lapolt at Yale New Haven Health and Dr. Mayur Desai for their incredible support and guidance throughout this endeavor. I would also like to thank Dr. Sten Vermund and the JDAT team at Yale New Haven Health for providing me with the data necessary for this analysis. Moreover, I would like to extend my deepest gratitude to my parents and friends for their continued support and encouragement during my academic pursuits.

Table of Contents

Abstract.....	2
Acknowledgements	3
Introduction.....	6
Methods	9
<i>Overview of Project</i>	9
<i>Patients</i>	10
<i>Data Collection</i>	10
<i>PHQ-2, PHQ-9, and CRRS</i>	
<i>Questionnaires</i>	10
<i>The National Comprehensive Cancer Network (NCCN) Distress</i>	
<i>Thermometer</i>	11
<i>Current</i>	
<i>Workflow</i>	12
<i>Data Analysis</i>	13
Results	15
<i>Characteristics of Patients</i>	15
<i>Distribution of Depression Scores</i>	16
<i>Distribution of Distress Scores</i>	16
<i>Distribution of Referral to Social Work</i>	17
<i>Reports of Self-Harm</i>	18

<i>Unconditional Logistic Regression Analysis</i>	18
Discussion.....	20
References	43
List of Tables	
Table 1: Patient Baseline Characteristics (N=6,192).....	28
Table 2: Distribution of PHQ-9 Scores (N=5,576).....	29
Table 3: Distribution of Distress Scores (N=5,396).....	31
Table 4: Referral to Social Work (N=192).....	32
Table 5: Description of Sample by Depression Score Categories (N=5,576).....	35
Table 6: Distribution of Distress Scores (N=5,396).....	37
Table 7: Unadjusted Associations Between Study Variables and Positive Self-harm Scores (N=62).....	38
Table 8: Multivariable logistic regression model on Validated Dataset of Factors Associated with Thoughts of Self-Harm.....	41
List of Figures	
Figure One: Current Workflow for Electronic Depression and Distress Process.....	42

Introduction:

There has been a greater emphasis on patient centricity and the patient's role in his or her medical care in recent years. Patient centricity is measured through patient-reported outcomes (PROs), defined as any report of the status of a patient's health condition that comes directly from the patient without interpretation of the patient's response by a clinician or anyone else.¹ Essentially, PROs capture how patients feel about their treatment, well-being, and symptoms. PROs have garnered medical providers' attention for their beneficial effects on patient health, such as improving quality of life (QoL) and treatment-related side effects.² Thus, it is recommended that PROs be implemented into routine cancer care.

Compared to its peak in the 1990s, cancer mortality has been steadily decreasing in the United States due to advancing medical treatments and early cancer screening programs, leading to improved survivorship in cancer patients.³ Cancer mortality has decreased continuously from 1991 to 2018 for a total decline of 31%, translating into 3.2 million fewer cancer deaths.⁴ Given that most cancers have transitioned from acute, life-threatening diseases to chronic ones, there has been growing concern with the application of PROs, such as distress and depression screenings, to improve post-cancer care since prolonged cancer prognosis does not necessarily equal better QoL. Although distress and depression screenings have been validated and widely disseminated in family care practices⁵, the uptake of screening tools for the psychological care and intervention of oncology patients has not been fully integrated into most cancer centers. Hence, to improve oncology care, payers have implemented hospital mandates to screen for distress and depression in cancer patients to improve health and alleviate costs⁶.

Given that the 5 year-relative survival from cancer is 67.4%, approximately 25% of cancer patients suffer from clinical depression after receiving a cancer diagnosis, fearing death,

recurrence, and treatment side effects.⁷ Unfortunately, clinicians often dismiss serious, depressive symptoms in cancer patients, assuming sadness and depression are part of the normal, emotional repertoire of oncology patients.⁸ Although it is expected for cancer patients to feel saddened about their diagnosis, clinical depression and distress are categorically different from temporary sadness and require immediate psychological intervention.⁹ Sadness is a normal human emotion that fluctuates over time and can be appropriately managed with strong family support and/or lifestyle changes; however, cancer patients suffering from clinical depression suffer from physical and psychological symptoms that significantly impair their quality of life for a prolonged period.¹⁰ About 70% of depressed cancer patients do not receive appropriate help, and only 5% of patients consult a medical professional.¹¹ Suicide risk in cancer patients is four times higher than in the general population, and this risk is the highest in the first year of diagnosis.¹² Moreover, the incidence of suicide death in cancer patients was 39.72 per 100,000 person-years.¹³ Therefore, PROs are crucial for detecting depression and distress in a timely and accurate manner so that patients' QoL and survivorship improves. PROs also glean incredible insight on how depression and distress scores, as well as important factors like cancer subtype, age, sex, and gender, may affect a patient's thought of self-harm throughout his or her cancer trajectory. Hence, if appropriately utilized, PROs of distress and depression screenings could improve cancer patients' mental health by referring them to social workers, psychologists, or psychiatrists for appropriate interventions and offer holistic patient-centric care.

The driving motivation for collecting PROs in oncology patients stems from the Center for Medicare and Medicaid Innovation (CMMI) incentivizing distress and depression screenings in routine medical care via the oncology care model (OCM), a program that improves patient health while minimizing healthcare expenditures.¹⁴ OCM encourages a multidisciplinary

approach to healthcare by mandating the use of social workers, who can assist cancer patients in an array of supportable services like financial and nutritional support. Among the 13 care components enlisted by the OCM framework, two of them require the involvement of social work services: Advance care plans and Distress and Depression screening.¹⁵ The latter mandate encourages clinicians to address patients' psychosocial health needs in a holistic manner while ensuring cancer patients are receiving necessary help. Ultimately, OCM is a payment model that tethers financial rewards to provider accountability and proper cancer patient management. The OCM framework incentivizes systematic efficiency in care centers by providing additional payments in 6-month increments for each active cancer patient and encouraging a savings program for chemotherapies and drugs if overall costs are lowered.¹⁴

As of January 2020, 138 practices are participating in OCM, with the Smilow Cancer Hospital at Yale-New Haven Health (YNHH) being one of the four participating care centers in Connecticut.¹⁶ Within the Smilow Cancer Hospital, the OCM performance metric accounts for the number of patients appropriately screened and followed up within 24 hours, which results in bonus payments—this Pay for Performance model rolled-out in January 2019. Thanks to these financial incentives, cancer care centers within the YNHH network have piloted the collection of distress and depression PROs within the electronic medical record workflow.

Prior to the initiation of this new electronic PRO process in 2018 at Smilow Cancer Hospital and Care Centers, depression and distress screening had low compliance rates due to a lack of standardized workflow. Screenings were done on paper, not collected from all patients, and were not patient-reported. In turn, compliance rates for completed the surveys were low: 26% for depression screening and 40% for distress. Additionally, depression and distress

screenings were not patient-reported since the depression and distress questionnaires were completed by an OCM Care Coordinator and a nurse, respectively.

The purpose of this study was to determine the feasibility of implementing the distress and depression PROs via the electronic medical record in three Smilow Cancer Hospital Care Centers and examining differences in depression and distress by various demographic and clinical characteristics. These analyses will provide preliminary results of feasibility, rates of depression and distress, and referrals for treatment. These findings will provide necessary information for disseminating and implementing these PROs and improving early detection of depressive and distress symptoms.

Methods:

Overview of Project

In November 2018, we conducted a pilot program that electronically screened all ambulatory cancer patients for distress and depression symptoms at three Smilow Cancer Hospital Cancer Care sites: The Smilow Cancer Hospital Breast Center, Guilford Care Center, and the Care Center at Torrington. The study was conducted in multiple phases, with a preparatory phase beginning in November 2018 and the remaining two phases of roll-outs beginning in April 2019 and August 2019. Smilow Breast Center and Guilford went live in April 2019, and Torrington Care Center followed in August 2019. The study continued until March 2020. At these study sites, patients completed the PHQ-2 and PHQ-9 surveys and Distress Thermometer screening on iPads while in the waiting room, who were then alerted in real-time by providers regarding referrals and interventions. Also, in compliance with the new Joint Commission mandate, the YNHH screen policy implemented the Columbia Suicide Severity Rating Scale (CSSRS) to assess patients with suicide ideation.

Patients

The scope of the program included all adult patients diagnosed with cancer who were seen for a clinic visit at Smilow, Guilford, and Torrington Care Centers. Patients who were seen for imaging or procedure visits were not assigned the surveys.

Data Collection

Information on patient age, sex, race, gender, diagnosis dates, PHQ-9, PHQ-2, and distress scores were collected from EPIC electronic medical records provided by the JDAT team at Yale New Haven Health.

PHQ-2, PHQ-9 and CRRS Questionnaires

The PHQ-2 is a 2-question survey that acts as the first-line approach for depression and anhedonia screening over the past two weeks.¹⁷ The PHQ-2 score ranges from 0-6: If a patient scores a 3 or higher, then a major depressive episode may likely occur. Patients who screen positive for depression should complete the PHQ-9 to determine if they are at risk for a depressive disorder.¹⁷ However, if the patient scores a 3 or less on the PHQ-2 survey, the patient has a negative depression score which does not necessitate an intervention (Figure 1).

The PHQ-9 is a 9-question survey that measures depression severity, with the first two questions stemming from the PHQ-2. Scores of 1-4, 5-9, 10-14, 15-19, and 20-27 act as thresholds for minimal, mild, moderate, moderately severe, and severe depression, respectively.¹⁸ Minimal depression does not necessitate an intervention. The last question on the survey screens for suicide risk and self-harm, which requires emergency assessment and intervention. This question asks: "Thoughts that you would be better off dead or thoughts of hurting yourself in

some way?" If patients answer with "several days", "more than half the days", or "nearly every day", then they must remain in the clinic and have a social worker evaluate them with the Columbia Suicide Severity Rating Scale (CSSRS).¹⁹ The CSSRS is an evidence-based tool that assesses suicidal ideation. For patients who screen positive for suicidal ideation (moderate or high) then a suicide risk assessment is done by a healthcare provider or a social worker, who then asks about the patient's plan, intent, or self-harm behaviors. If the patient is considered high risk of suicide, a healthcare provider, social worker, or nurse must stay with the patient until he or she is transferred to the emergency department (Figure 1).

Under the "Preventive Care and Screening: Screening for Depression and Follow-Up Plan" of the Oncology Care Model, a percentage of cancer patients 18 years and older who were screened for depression every 6 months upon their first encounter and if screened positive, should pursue follow up. Follow-up plans include suicide risk assessment, referral to a practitioner for the treatment of depression, pharmacological interventions, and more.²⁰

The National Comprehensive Cancer Network (NCCN) Distress Thermometer

Distress is measured through the National Comprehensive Cancer Network (NCCN) Distress Thermometer, an evidence-based tool that helps providers provide support to oncology patients.²¹ The tool measures distress from a score of 0-10, and if patients report a score greater than or equal to four, which indicates moderate to extreme distress, clinical judgment is required, and a physician will be notified of the score. If the patient scores a 4 or lower on the NCCN distress questionnaire, the patient has negative distress and does not require an intervention; however, if a distress score of 4 or more is recorded, then based on the score on the Distress Screening tool, referrals could be made to a social worker, chaplain, nutritionist, or psychiatrist.²²

(Figure 1). Although distress screening must be assessed at a minimum of one time, all patients should be screened at every medical visit. If this is not possible, patients should be screened at their first visit and at appropriate, timely intervals per the NCCN guidelines.²³ Also, according to the Commission on Cancer, all cancer patients must be screened for distress a minimum of once per pivotal medical visit as determined by the program.²⁴

Current Workflow

When a patient arrives at check-in, the staff determines if they need to complete distress and depression surveys based on their department-appointed reported visit or DAR. Questionnaires are administered on the first visit and then every 90 days after the initial visit. Staff at the front desk are trained to answer questions patients may have regarding the screening program, such as “Who will receive the results?” and “What is this used for?” If asked these questions, the staff will answer “Your Smilow care provider team”, and “To better meet your physical and emotional needs”, respectively. Once they agree to complete the screening, the patient completes the Distress Screening and PHQ-2 on the iPad; if the patient screens positive on the PHQ-2 survey, then they will complete the PHQ-9. If the patient refuses to answer the questionnaire, the front desk will document it through the DAR. Options for non-participation include language barriers, technology issues, lack of an iPad, and general refusal. If the distress and depression screenings are negative (distress ≤ 4 and PHQ-2 < 3), the results are filed and no intervention is necessary. If the screening is positive (distress ≥ 4 and/or positive PHQ-2 ≥ 3), then the system notifies the provider to review the results in EPIC through the best practice advisory (BPA), which are reminder tools within EPIC electronic health records that provide clinical decision support. Once alerted of positive depression and/or distress scores by the BPA,

the provider will document an action plan and talk to the patient. Referral options under EPIC include: “Referral to Social Work”, “Referral to Psychiatry”, and “Referral to Psychology”. Other action plans may not require referral but instead include: continued care with an existing mental health provider, discussing pertinent distress symptoms and providing counseling, and reviewing and adjusting medications. BPA will notify the provider if the patient has answered the self-harm question with an exclamation mark. Depression scores that are considered moderately severe and severe are also represented with a bright, yellow icon. If the patient has a positive self-harm response, then either a social worker or a nurse will stay with the patient until the patient is transferred to the Emergency Department (Figure 1).

Data Analysis

Statistical analyses were conducted with the SAS 9.4 statistical software. Baseline data were stratified on variables such as age, sex, race, cancer center, time since cancer diagnosis, and cancer type. Since the PHQ-9 and the distress questionnaire allowed patients to input exact, numerical responses to all questions, we based each category of depression and distress criteria on appropriate thresholds for validated score ranges: For example, depression and distress scores were categorized into their appropriate criteria (minimal, mild, moderate, moderately severe, and severe depression and negative and positive distress, respectively) and were descriptively analyzed as categorical variables across all previously mentioned covariates. The threshold for the variable, “time since a patient's first cancer diagnosis”, was determined at six months since the onset of the COVID-19 pandemic terminated data collected after 11 months. Hence, all patients in the sample did not have a period of 1-year post initial cancer diagnosis. Statistical

comparisons of categorical depression and distress scores were performed with the Fisher Exact test with a Monte Carlo simulation.

For analytical purposes, the characteristic “Referral to Social work”, was categorized as a dichotomous variable with two outcomes: Patients referred to social work or treated with a different intervention. As a variable, “Referral to Social Work” encompassed numerous related treatment options, which included, “Referral to Social work; Discussed pertinent distressing symptoms and provided counseling”, “Medications reviewed and added or adjusted as needed; Referral to Social work”, and simply, “Referral to Social work”. Social work was an intervention of interest to the study since OCM purports the need for integrated, multidisciplinary cancer care that includes psychosocial work plans produced by social workers.

We used simple and multivariate unconditional logistic regression models to identify key exposure variables and predictors on the binary outcome of self-harm. The primary exposure variables were categorical scores of depression. Key covariates included age, sex, race, cancer center, time since cancer diagnosis, cancer type, and distress scores. The binary outcome of self-harm was split into two categories depending on the patients’ answer to the last question of the PHQ-9 questionnaire—“Thoughts that you would be better off dead, or thoughts of hurting yourself in some way?”—and their respective PHQ-9 score. If the patient scored a 0 on the last PHQ-9 question, then they were not at risk of self-harm or suicide; however, if an individual answered a 1, 2, or 3, then the patient was considered high-risk of self-harm and suicidal thoughts. The reference categories for age, sex, race, cancer center, time since cancer diagnosis, cancer type were patients aged 25-44 years old, males, White or Caucasians, Smilow Breast Cancer Center, patients with less than six months since cancer diagnosis, and all other cancers, respectively. The reference variables for depression and distress criteria were negative

depression and negative distress, respectively. Discovery modeling was performed in a 50% split of the total sample, creating two randomly assigned discovery and validation datasets compared across selected parameter estimates to test for equivalence, reliability, and external validity. The sensitivity and specificity were also determined for each multivariate regression model. Additionally, the goodness of fit of each multivariate logistic model was estimated with the Hosmer-Lemeshow test.

Results:

Characteristics of Patients

A total of 6,192 patients from Smilow Breast Cancer Center, Torrington Care Center, and Guilford Care Center were part of the study from April 2019 to March 2020, with 49.3% of patients from Smilow, 21.3% from Torrington, and 29.3% from Guilford. The mean age was 66.8 ± 13.0 years, and 81.7% of participants were women (Table 1). There were more females than males in the sample; more than half of the participants were admitted to Smilow, where 98.9% of survey respondents were female. The most common reasons for non-participation in the distress and depression screenings included language barriers, technology issues, and general refusal. Therefore, 5,396 patients completed the distress survey, and 5,576 patients completed the PHQ-9 questionnaire. The top six most reported cancer subtypes across all three cancer centers were: Breast cancer, chronic lymphocytic leukemia, malignant melanoma, prostate cancer, myeloma, and colon cancer. These six cancer subtypes accounted for 64.8% of all reported cancers. The most reported cancer subtype was breast cancer, which accounted for 55.5% of all cancer diagnoses. 82.6% of all participants were White, and most patients were diagnosed within the past 6 months, with 11.5% diagnosed more than 6 months prior (Table 1).

Distribution of Depression Scores

The mean and median score of the total PHQ-9 score was 0.81 ± 2.73 and 0, respectively. Outcomes for each survey were skewed to the right since the majority of patients reported low scores of 0 or 1 on the PHQ-9 survey: 79.2% of study participants had a total PHQ-9 score of 0. The highest reported depression score was 27 with a cumulative frequency of 0.04%. Also, 16.1%, 1.67%, 1.69%, 0.92%, and 0.34% of cancer patients were in the minimal, mild, moderate, moderately severe, and severe categories of depression, respectively. (Table 2)

A total of 94.7% of study participants had a PHQ-2 score < 3 , which does not require an intervention from the provider (Table 2 and 3). The remaining 5.30% of participants scored a 3 or higher on the PHQ-2 survey and had to complete the PHQ-9, which necessitated intervention. (Table 2). 52.6% of patients aged 45-64 and 36.8% of patients aged 65-84 reported severe depression compared to 10.5% of 25-44 year olds and 0% of 85+ year olds with severe depression ($p\text{-value} < 0.001$). Additionally, 78.9% of females reported severe depression compared to 21.1% of males ($p\text{-value} < 0.001$) with severe depression. 47.4% of patients with breast cancer were severely depressed compared to 5.26% with myeloma and 47.4% with other cancer types who were severely depressed ($p\text{-value} < 0.001$). 84.2% of patients with less than 6 months since diagnosis reported severe depression compared to 15.8% of patients with more than 6 months since diagnosis who were severely depressed. ($p\text{-value} < 0.001$). (Table 5)

Distribution of Distress Scores

The mean and median score of the distress survey was 1.79 ± 2.32 and 1.00, respectively (Table 4). Similar to the non-parametric distribution of depression scores, most of the distress were skewed to the right: 45.3% of participants had a total distress score of 0. Furthermore,

81.4% of cancer patients had a negative distress score (distress \leq 4). Additionally, 18.6% of patients reported positive distress scores. The highest reported distress score was a 10 with a frequency of 0.73%. (Table 3)

48.9% of patients who were 45-54 year olds reported positive distress compared to 7.41% of patients aged 25-44 year olds, 39.2% of patients aged 65-84 year olds, and 4.50% of patients who were 85+ year olds with positive distress. There were 89.7% females who reported positive distress scores compared to 10.3% males with positive distress. Additionally, 85.0% of patients who were White had positive distress compared to 5.52% patients who were Black or African American, 1.91% of Asian patients, 3.20% of other races, and 4.34% of patients who refused to disclose their race with positive distress (p-value= <0.001). There were 30.8% breast cancer patients who reported positive distress compared to 30.8% patients suffering from other cancer types, 1.50% chronic lymphocytic leukemia patients, 1.30% malignant melanoma patients, 0.50% prostate cancer patients, and 0.10% colon cancer patients with positive distress. There were 87.1% of patients with less than 6 months since their cancer diagnosis who had positive distress compared to 12.9% of patients more than 6 months since their cancer diagnosis with distress. There were 68.2% of patients seen at Smilow Breast Cancer Center with positive distress compared to 10.0% and 21.8% of patients to Torrington and Guilford with positive distress, respectively. (Table 6)

Distribution of Referral to Social Work

In total, there were 192 patients who were referred to social work per OCM recommendations, which comprised 15.2% of all interventions administered for distress and depression. Moreover, all 257 patients who were at risk of depression and/or 999 patients at risk

of distress were referred to appropriate interventions, which included, “Counseling provided to patient, no mental health referral required”, “Medications reviewed and added or adjusted as needed”, and “Continue care with existing mental health provider; Discussed pertinent distressing symptoms and provided counseling”. Therefore, there was a 100% intervention rate in this program.

Reports of Positive Self-Harm

In total, 62 oncology patients had positive self-harm responses, which comprised 1.00% of the total sample. Out of the 712 patients who answered the last question on the PHQ-9, 8.71% of patients tested positive for self-harm. Positive self-harm scores were reported across all depression and distress criteria and recorded across all age groups, sexes, races, cancer centers, times since cancer diagnosis, and cancer types. Additionally, 33.3%, 20.4%, and 12.8% of patients with severe, moderately severe, and moderate levels of depression reported positive self-harm scores. Also, 14.1% of patients with positive distress reported positive self-harm scores. Patients with the highest frequency of positive test scores were aged 25-44 (14.8%). Also, 10.5% of males had positive self-harm scores compared to 8.10% of females. (Table 7)

Unconditional Logistic Regression Analysis

The simple, unadjusted logistic regression model looked at each predictor variable separately and analyzed their individual effects on self-harm. For the unadjusted logistic regression model, the parameter estimates were similar for the discovery and validated models, and the parameter estimates for the validated model were reported. Hence, the unadjusted model is a reliable predictor of self-harm.

The multivariate analysis was also conducted for both discovery and validation datasets as well as sensitivity and specificity analyses. However, the groups were discrepant in terms of the key predictors selected in their respective stepwise, multivariate logistic regression models. The discovery model selected for patients who refused to disclose their race, people of other races, patients aged 45-64, patients with positive distress, and patients with prostate cancer; however, patients of other races were not a significant predictor in the stepwise regression for the discovery model. Meanwhile, the validated model selected for female patients, patients seen at Guilford, patients seen at Torrington, patients with prostate cancer, and patients suffering from severe and moderately severe depression. In the discovery regression model, prostate cancer is more correlated with the outcome and had a significant p-value; however, in the validated stepwise regression model, prostate cancer was a not statistically significant predictor (p-value=0.06) of self-harm. Additionally, In the validated stepwise logistic regression model, the p-value was not statistically significant for female patients (p-value=0.13) and was not statistically significant for patients seen at Torrington (p-value=0.14). Since the selected variables and the parameter estimates for the discovery and validation dataset were different, the validated model should be interpreted with caution.

The p-value for the Hosmer and Lemeshow test was 0.87 for the validated model, meaning that we can reject the null hypothesis and conclude that the model accurately predicts the probability of self-harm. However, the stepwise logistic regression for the validated dataset may not indicate the model's reliability to predict self-harm due to the discrepant parameter estimates observed during the discovery modeling.

Both the validation and discovery data tests had high specificity and low sensitivity values. The specificity, or the true negative rate, is the proportion of true negative responders to

the self-harm question who had a negative result on the last question on the PHQ-9 survey. The specificity for the validated and discovery models were 99.4% and 100%, respectively. On the other hand, the sensitivity, or the true positive rate, is the proportion of true positive responders who had a positive result to the last question on the PHQ-9. The sensitivity for the validated and the discovery models were 11.8% and 0.00%, respectively. The parameter estimates of sensitivity and specificity are different in both models. However, if only considering the validated dataset, the multivariate regression model was able to identify a positive result for 11.8% of people suffering from harmful or suicidal thoughts and find a negative result for 99.4% of patients who did not suffer from self-harm or suicidal thoughts.

In the validated, multivariate stepwise logistic regression, the statistically significant predictors were patients seen at Guilford, patients suffering from severe depression, and patients with moderately severe depression. Compared to patients seen at Smilow and Torrington, patients seen at Guilford had 0.17 lower odds (CI: 0.05-0.66) of reporting a positive self-harm response. Compared to patients with minimal, mild, moderate depression, patients with moderately severe depression had 3.72 (CI: 1.24-11.2) higher odds of reporting self-harm. Also, compared to patients with minimal, mild, moderate depression, patients with severe depression had 8.23 (CI: 1.72-39.3) higher odds of reporting self-harm. (Table 8)

Discussion:

This analysis examined the prevalence of depression and distress scores in oncology patients who participated in the new, electronic workflow piloted by Smilow Cancer Hospital. This analysis also identified predictors for self-harm and suicidal thoughts as an effort to

understand if this outcome is predicted by depression while considering key covariates like age, sex, race, cancer center, time since cancer diagnosis, distress, and cancer type.

Although the majority of patients reported negative depression and distress scores, it is imperative to focus on patients who reported positive distress and PHQ-9 scores since they require timely and immediate action plans from providers. Previous meta-analyses have indicated variability in prevalence rates of depression that range from 0% to 46% for cancer patients.²⁵ In this study, 81.4% of patients reported negative distress. Moreover, 94.7% of patients reported negative depression since their PHQ-2 score was less than 3—this also includes the depression criteria for minimal depression (PHQ-9 score between 1-4), which does not necessitate provider intervention. 18.6% of patients had positive distress, and 5.30% had positive PHQ-9 Scores indicating depression. For those with positive PHQ-9 scores, 1.67%, 1.69%, 0.92%, and 0.34% had mild, moderate, moderately severe, and severe depression, respectively. According to existing literature, prevalence estimates for major depression—which includes moderate, moderately severe, and severe depression—and minor depression—which includes mild and minimal depression—are 15% and 10% in cancer patients, respectively.²⁶ In this program, 2.95% had major depression, and 17.8% had minor depression. Although this study had lower rates of major depression and higher rates of minor depression, it is crucial to prioritize patients with moderate, moderately severe, and severe depression since it has been indicated that major depression can lead to worse outcomes.

Patients who comprised the highest percentages of severe depression were patients aged 45-64 years old, were females, were White, and had breast cancer. Previous literature suggests that depression is most common in pancreatic and lung cancers⁸; however, breast cancer patients in our study had the highest frequencies of depression across all depression criteria. This finding

could be attributed to the fact that 98.9% of patients who completed the distress and depression surveys at Smilow Breast Cancer were women. Since most of the sample was comprised of female breast cancer patients, future studies should examine a more diverse sample.

Previous work has indicated that mental illness is a key predictor of suicidality in cancer patients and that a strong relationship exists between depression and suicide risk.¹³ In fact, more than 90% of people who committed suicide have depression or another underlying mental illness.²⁷ Previous work indicated that depressive episodes, pain, and a lack of social network are root causes for suicide ideation in cancer patients.²⁸ In our study, the multivariate regression model indicated that patients who were at risk of self-harm and suicidal thoughts were those with prostate cancer, patients with severe depression, and patients with moderately severe depression. Compared to negative, minimal, mild, and moderate depression, the odds ratio of reporting self-harm scores was 3.72 (CI: 1.24-11.2) for moderately severe depression and 8.23 (CI:1.72-39.3) for severe depression. Although these findings correspond with current literature regarding depression as a risk factor for suicide, they do not account for other important factors such as poor social support, hopelessness, advanced cancers, and delirium on self-harm risk.²⁸ Moving forward, Smilow Cancer Hospital should consider the effects that moderately severe and severe depression have on self-harm and encourage providers to recognize the importance of maintaining a supportive rapport with patients while treating major depressive symptoms appropriately. The multivariate regression model indicated that the last question on PHQ-9 had a high specificity (99.4%) and lower sensitivity (11.08%), implying that the last question, "Thoughts that you would be better off dead, or thoughts of hurting yourself in some way?", was able to detect true negative responders given depression as the primary exposure. Current

literature notes that the diagnostic sensitivity of PHQ-9 scores >10 has a sensitivity of 88%, but more research is needed regarding the diagnostic validity of the last question.²⁹

When tethered with depression screening, routine distress screening of cancer patients can improve overall care when accompanied with psychosocial treatment. Previous studies indicated that 25-30% of newly diagnosed cancer patients have high levels of distress.³⁰ In our study, 87.1% of cancer patients diagnosed in the past 6 months had a positive distress score compared to 12.9% of cancer patients with more than 6 months since their initial diagnosis. Hence, it is critical for physicians to appropriately refer these patients to holistic, patient-centric treatment options like social workers. Social workers are essential for addressing numerous psychosocial interventions and are at the forefront of developing plans that pinpoint patients' distress.

Although patients may have a negative distress score or a negative depression score, they could still be at risk of self-harm and suicidal thoughts. Our results indicate that 5.58% of patients with negative distress and 8.11% of patients with minimal depression had positive self-harm responses. To that extent, depressive symptoms, even mild ones, can still deleteriously impact a patient's cancer trajectory and decrease their quality of life, ultimately contributing to suicide.¹³ Moreover, incident depression holds tremendous clinical value in early detection of suicide and therefore should not be overlooked by providers.¹³ Studies have also indicated that actual suicide rates are higher in men than in women³¹, which shed insight into the reported frequencies of positive self-harm by males and females in cancer patients, which were 10.5% and 8.10%, respectively. Previous findings have also indicated that the first six months after a cancer diagnosis is an incredibly stressful period that can increase the risk of suicide in cancer patients.³² Unsurprisingly, 87.1% of Yale cancer patients with less than 6 months since their

diagnosis suffered from positive distress compared to 12.9% of Yale cancer patients with more than 6 months since diagnosis. However, the difference in self-reported self-harm scores was marginally different between patients who had less than 6 months since diagnosis (7.73%) versus patients who had more than six months (8.95%). Previous work has indicated that suicide rates in cancer patients decrease years after diagnosis; nevertheless, it is imperative that physicians adequately assess suicidal tendencies during the early, critical period of elevated suicidal ideation.¹³ Although physicians may not be able to prevent the chronic medical effects of cancer, they have a responsibility to prevent psychological and psychosocial fall-out. Hence, early depression and distress screenings and effective treatments are critically important for reducing the cost associated with cancer and improving cancer patients' quality of life.

Additionally, previous meta-analyses have indicated that patients with prostate cancer have significantly higher suicide rates per 100,000 person-years compared to other cancers, which parallels the high percentage of patients with prostate cancer (44.4%) reporting positive self-harm in this study.³³ Existing literature has also indicated that patients who have been diagnosed with prostate, lung, colon, and breast cancer were also more likely to report positive scores of self-harm.³⁴ In our study, 4.00% of patients with colon cancer, 8.68% of patients with breast cancer, 4.00% of patients with myeloma reported positive scores of self-harm. Additionally, 6.25% of Yale patients with chronic lymphocytic leukemia and 8.23% patients with other cancers also reported positive self-harm scores. Existing literature demonstrated that patients with breast cancer had an elevated risk of suicidality compared to patients with other cancers and that elderly men with prostate cancer and men with myeloma were also at increased risk of self-harm.³⁵ In a prospective study carried out in cancer patients in the UK, patients who reported thoughts of self-harm were significantly younger than the rest of the cohort.³⁴ Similarly,

14.8% of Yale cancer patients aged 25-44 years old reported positive self-harm scores, which was higher than the reported positive self-harm scores by 45-64 year olds (6.46%), 65-84 year olds (8.75%), and patients 85+ years of age (11.5%). Ultimately, future studies at Yale New Haven Health should also gauge the impact of chronic lymphocytic leukemia on self-harm as well as other social factors, such as marital status, religious beliefs, and family support on suicide risk.

The study's greatest strength was its ability to refer everyone at risk of depression and distress to appropriate interventions. The EPIC workflow and the BPA notification system enabled physicians to create action plans when notified of a positive depression and/or distress score through the electronic workflow. Furthermore, the Oncology Care Model encouraged the use of social work to treat numerous facets of patients' emotional and psychosocial repertoire. 15.2% of patients who received interventions were referred to social work; although some action plans may not elicit the help of a social worker, it is important that physicians recognize the importance of social workers in the multidisciplinary framework of medicine and the social worker's role in improved health outcomes. Additionally, the brevity of both the distress and depression surveys assures greater completion of data while reducing participant fatigue. As such, the electronic surveys were quick and straightforward to fill out, taking approximately 5 minutes to complete.

There are several limitations regarding the study's design and timeframe. Given that this study was a pilot program implemented for a short period of 11 months, data regarding follow-ups and the effectiveness of specific psychological or lifestyle interventions were not collected. In the same regard, data on lower total scores of PHQ-9 or distress do not exist, and conclusions cannot be drawn on the overall effectiveness of the standardized, electronic workflow for

depression and distress. Also, the program was primarily composed of White women, which affects the generalizability of these findings.

Every participant has a vital role to play in improving patient health efficiently and effectively. Although PROs are helpful in clinical management, it has been challenging to implement in clinical settings: Time, expenses, and adequate assessment measures are several significant burdens preventing the widespread use of PROs in routine healthcare practice. When considering PRO implementation programs, it is crucial to monitor and adjust for these caveats and setbacks, especially within their early phases. Factors affecting the implementation of these PROs include overwhelmed physicians, technology and software issues, confusion about the workflow, and lack of resources for positively screened patients. Additionally, patients who completed the questionnaires experienced several pros and cons with the new electronic workflow. Patients also voiced a preference for the iPad over paper since the latter method was tedious, burdensome, and required interpretation of a nurse practitioner. In the future, special circumstances should be considered in the assessment of distress and depression, such as cultural sensitivity, language barriers, and provisions for people with cognitive impairments.

Looking forward, the leadership at Smilow Cancer Center should consider collecting PRO data as frequently as possible without overburdening patients. In the case of the PHQ-2/PHQ-9 and distress questionnaires, the overarching goal of this new electronic workflow is to understand if a patient's depression and/or distress changed from baseline to a future point in time after administration of a particular intervention. Unfortunately, as of December 2019, the SARS-CoV-2 pandemic has temporarily halted this new electronic screening program. Once Smilow Cancer Hospital reinitiates this pilot study, leadership at Yale New Haven Health can assess if PROs and provider interventions and action plans improved patients' distress and

depression symptoms. Moreover, it is important to employ personnel who can help patients complete the distress and depression surveys to increase compliance and reduce missing data without influencing their response.

Furthermore, the SARS-CoV-2 global pandemic has emphasized the need for PROs and precision medicine for cancer patients: the onslaught of a severe, contagious respiratory illness has increased the need for telemedicine and remote monitoring of patients. As patients become further removed from their physicians, patient-centric care carries more importance; therefore, clinicians need to administer appropriate interventions despite resource constraints so that cancer patients can improve their distress and depression symptoms. Consequently, cancer hospitals should incorporate PROs for distress and depression screening in electronic questionnaires that can be done at home to assess for mental health during these troubling times.

In sum, PROs are incredibly important for improving quality of life since physicians may mistakenly dismiss severe depressive symptoms as normal emotional responses to cancer. PROs can address the issue of therapeutic nihilism, which prevents clinicians from differentiating clinical depression from normal sadness. The electronic screening workflow is the right step towards increasing PRO compliance in cancer patients.

List of Tables:

Table 1: Patient Baseline Characteristics (N=6,192)

Characteristic	N ^a	N%
Age (years), mean±SD	66.8 ± 13.0	
Sex		
Male	1264	18.3%
Female	5656	81.7%
Race		
White or Caucasian	5715	82.6%
Black or African American	432	6.24%
Asian	133	1.92%
Other	268	3.87%
Patient Refused	372	5.38%
Cancer Type		
Breast Cancer	3843	55.5%
Chronic lymphocytic leukemia	196	2.83%
Malignant Melanoma	123	1.78%
Prostate Cancer	126	1.82%
Myeloma	101	1.46%
Colon Cancer	93	1.34%

Other cancers	2439	35.2%
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Time Since Diagnosis

More than 6 months since diagnosis	795	11.5%
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Less than 6 months since diagnosis	6126	88.5%
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Site

Smilow	3414	49.3%
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Torrington	1477	21.3%
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Guilford	2030	29.3%
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Table 2: Distribution of PHQ-9 Scores (N=5,576)

Characteristic	N ^a	N%
PHQ-9 Scores, mean±SD	0.81 ±2.73	
PHQ-Scores		
0	4417*	79.2%*
1	421*	7.55%*
2	441*	7.91%*
3	18	0.32%
4	19	0.34%
5	20	0.36%

6	20	0.36%
7	23	0.41%
8	12	0.22%
9	18	0.32%
10	19	0.34%
11	21	0.38%
12	20	0.36%
13	14	0.25%
14	20	0.36%
15	11	0.20%
16	16	0.29%
17	11	0.20%
18	9	0.16%
19	4	0.07%
20	5	0.09%
21	6	0.11%
22	3	0.05%
23	2	0.04%
24	3	0.05%

25	0	0.00%
26	0	0.00%
27	2	0.04%

Categories of Depression

No depression	4417	79.3%*
Minimal	899	16.1%*
Mild	93	1.67%
Moderate	94	1.69%
Moderately Severe	51	0.92%
Severe	19	0.34%

*Also equivalent to a PHQ-2 score less than 3

Table 3: Distribution of Distress Scores (N=5,396)

Characteristic	N ^a	N%
Distress Scores, mean±SD	1.79 ±2.32	
Distress Scores		
0	2435	45.3%
1	717	13.4%
2	681	12.7%
3	539	10.0%

4	247	4.60%
5	253	4.71%
6	143	2.66%
7	160	2.98%
8	114	2.12%
9	43	0.80%
10	39	0.73%
11	0	0.00%
12	0	0.00%
13	0	0.00%
14	0	0.00%

Categories of Distress

Negative Distress	4327	81.4%
Positive Distress	999	18.6%

Table 4: Referral to Social Work (N=192)

Characteristic	N ^a	N%
Referral Rate		
Social Work	192	15.2%

Other interventions	1064	84.8%
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Age (years)

25-44	26	13.5%
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45-64	93	48.4%
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65-84	72	37.5%
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85+	1	0.52%
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Sex

Male	17	8.85%
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Female	175	91.2%
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Race

White	128	78.5%
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Black or African American	15	9.20%
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Asian	4	2.45%
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Other	8	4.91%
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Patient Refused	8	4.91%
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Cancer Type

Breast Cancer	126	65.6%
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Chronic lymphocytic leukemia	0	0.00%
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Malignant Melanoma	1	0.52%
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Prostate Cancer	0	0.00%
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Myeloma	0	0.00%
Colon Cancer	2	1.04%
Other cancers	63	1.04%

Time Since Diagnosis

More than 6 months since diagnosis	47	24.5%
Less than 6 months since diagnosis	145	75.5%

Site

Smilow	151	78.7%
Torrington	21	12.5%
Guilford	17	8.85%

Depression Scores

Severe	5	2.60%
Moderately Severe	13	6.77%
Moderate	17	8.85%
Mild	6	3.13%
Minimal	58	30.2%
No depression	93	48.4%

Distress Scores

Positive Distress	102	53.1%
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Negative Distress	90	46.9%
Answer to Self Harm Question		
Positive	21	28.0%
Negative	54	72.0%

Table 5: Description of Sample by Depression Score Categories (N=5,576)

Characteristic	Depression Scores						P Value (Fisher Exact Test)
	No depression (N, %)	Minimal depression (N, %)	Mild depression (N, %)	Moderate depression (N, %)	Moderately severe depression (N, %)	Severe Depression (N, %)	
Age (years)							
25-44	184 (4.17%)	59 (6.56%)	7 (7.53%)	9 (9.57%)	4 (7.84%)	2 (10.5%)	<0.001
45-64	1580 (35.8%)	371 (41.3%)	41 (44.1%)	34 (36.2%)	25 (49.0%)	10 (52.6%)	
65-84	2286 (51.8%)	493 (44.8%)	35 (37.6%)	46 (48.9%)	20 (39.2%)	7 (36.8%)	
85+	367 (8.31%)	66 (7.34%)	10 (10.8%)	5 (5.32%)	2 (2.62%)	0 (0.00%)	
Sex							
Male	858 (19.4%)	115 (12.8%)	15 (16.1%)	12 (12.7%)	9 (17.7%)	4 (21.1%)	<0.001
Female	3558 (80.6%)	784 (87.2%)	78 (83.8%)	82 (87.2%)	42 (82.35%)	15 (78.9%)	
Race							
White or Caucasian	3721 (84.2%)	728 (81.0%)	73 (78.5%)	66 (70.2%)	38 (74.5%)	13 (68.4%)	<0.001
Black or African American	237 (5.37%)	73 (8.12%)	14 (15.1%)	9 (9.57%)	4 (7.84%)	1 (5.26%)	

Asian	69 (1.56%)	23 (2.56%)	2 (2.15%)	5 (5.32%)	2 (3.92%)	0 (0.00%)
Other	132 (2.99%)	40 (4.45%)	2 (2.15%)	11 (11.7%)	5 (9.80%)	3 (15.8%)
Patient Refused	258 (5.84%)	35 (3.89%)	2 (2.15%)	3 (3.19%)	2 (3.92%)	2 (10.5%)

Cancer Type

<0.001

Breast Cancer	2332 (52.8%)	527 (34.3%)	53 (57.0%)	57 (60.6%)	24 (47.1%)	9 (47.4%)
Chronic lymphocytic leukemia	147 (3.33%)	14 (1.56%)	2 (2.15%)	0 (0.00%)	0 (0.00%)	0 (0.00%)
Malignant Melanoma	76 (1.72%)	11 (1.22%)	0 (0.00%)	1 (1.06%)	0 (0.00%)	0 (0.00%)
Prostate Cancer	87 (1.97%)	18 (2.00%)	1 (1.08%)	3 (3.19%)	2 (3.92%)	0 (0.00%)
Myeloma	69 (1.56%)	13 (1.45%)	1 (1.08%)	2 (2.13%)	0 (0.00%)	1 (5.26%)
Colon Cancer	51 (1.15%)	8 (0.89%)	1 (1.08%)	1 (1.06%)	0 (0.00%)	0 (0.00%)
All other cancer types	1655 (37.5%)	308 (34.3%)	35 (37.6%)	30 (31.9%)	25 (49.0%)	9 (47.4%)

Time Since Diagnosis

<0.001

More than 6 months since diagnosis	552 (12.5%)	173 (19.2%)	6 (6.45%)	6 (6.38%)	12 (25.5%)	3 (15.8%)
Less than 6 months since diagnosis	3865 (87.5%)	726 (80.8)	87 (93.6%)	88 (93.6%)	39 (76.5%)	16 (84.2%)

Site

Smilow	2035 (46.1%)	540 (60.1%)	59 (63.4%)	59 (62.8%)	32 (62.8%)	11 (57.9%)
Torrington	1053 (23.8%)	76 (8.45%)	8 (8.60%)	13 (13.8%)	9 (17.7%)	3 (15.8%)
Guilford	1329 (30.1%)	283 (31.5%)	26 (28.0%)	22 (23.4%)	10 (19.6%)	5 (26.3%)

Table 6: Distribution of Distress Scores (N=5,396)

Characteristic	Distress Scores		P-value
	Negative Distress (N, %)	Positive Distress (N, %)	
Age (years)			<0.001
25-44	202 (4.62%)	72 (7.41%)	
45-64	1549 (35.4%)	488 (48.9%)	
65-84	2254 (51.6%)	392 (39.2%)	
85+	367 (8.39%)	45 (4.50%)	
Sex			<0.001
Male	938 (21.5%)	103 (10.3%)	
Female	3433 (78.5%)	896 (89.7%)	
Race			<0.001
White	2022 (83.04%)	1647 (85.0%)	
Black or African American	135 (5.54%)	107 (5.52%)	
Asian	40 (1.64%)	37 (1.91%)	
Other	77 (3.16%)	6 (3.20%)	
Patient Refused	161 (6.61%)	84 (4.34%)	
Cancer Type			<0.001
Breast Cancer	2191 (50.1%)	308 (30.8%)	

Chronic lymphocytic leukemia	148 (3.39%)	15 (1.50%)	
Malignant Melanoma	81 (1.85%)	13 (1.30%)	
Prostate Cancer	100 (2.29%)	5 (0.50%)	
Myeloma	83 (1.90%)	5 (0.00%)	
Colon Cancer	69 (1.58%)	1 (0.10%)	
All other cancer types	1700 (38.9%)	308 (30.8%)	
Time Since Diagnosis			<0.001
More than 6 months since diagnosis	627 (14.3%)	129 (12.9%)	
Less than 6 months since diagnosis	3745 (85.7%)	870 (87.1%)	
Site			<0.001
Smilow	1870 (42.8%)	681 (68.2%)	
Torrington	1112 (25.4%)	100 (10.0%)	
Guilford	1390 (31.8%)	218 (21.8%)	

Table 7: Unadjusted Associations Between Study Variables and Positive Self-harm Scores (N=62)

Characteristic	N ^a	n (%) with positive self-harm scores	Unadjusted Odd Ratios
Age (years)			
25-44	54	8 (14.8%)	1.00

45-64	263	17 (6.46%)	0.63 (0.16-2.43)
65-84	323	30 (8.75%)	0.66 (0.18-2.46)
85+	61	7 (11.5%)	0.53 (0.08-3.49)

Sex

Female	568	46 (8.10%)	0.61 (0.28-1.33)
Male	153	16 (10.5%)	1.00

Race

Black or African American	60	3 (5.00%)	0.37 (0.05-2.84)
Asian	17	3 (17.7%)	3.46 (0.67-18.0)
Other	31	4 (16.1%)	1.48 (0.32-6.89)
Patient Refused	26	6 (23.1%)	3.46 (0.88-13.6)
White or Caucasian	587	45 (7.67%)	1.00 (1.00)

Cancer Type

Breast Cancer	334	29 (8.68%)	1.14 (0.54-2.41)
Chronic lymphocytic leukemia	16	1 (6.25%)	<0.001* (<0.001- >999.9)
Malignant Melanoma	11	0 (0.00%)	<0.001* (<0.001- >999.9)
Prostate Cancer	9	4 (44.4%)	10.4 (1.91-56.2)
Myeloma	25	1 (4.00%)	<0.001* (<0.001- >999.9)
Colon Cancer	10	1 (4.00%)	1.73 (0.19-15.4)

Other cancers	316	26 (8.23%)	1.00 (1.00)
Time Since Diagnosis			
More than 6 months since diagnosis	207	16 (7.73%)	0.91 (0.41-2.01)
Less than 6 months since diagnosis	514	46 (8.95%)	1.00
Site			
Smilow	354	36 (10.2%)	1.00
Torrington	81	14 (17.3%)	3.24 (1.39-7.54)**
Guilford	286	12 (4.20%)	0.32 (0.12-0.89)**
Depression Scores			
Severe	18	6 (33.3%)	10.3 (2.11-49.9)**
Moderately Severe	49	10 (20.4%)	6.84 (2.14-21.9)**
Moderate	86	11 (12.8%)	2.85 (0.95-8.52)
Mild	79	3 (3.80%)	0.40 (0.05-3.23)
Minimal	185	15 (8.11%)	2.08 (0.79-5.46)
No depression	304	17 (5.59%)	1.00
Distress Scores			
Positive Distress	255	36 (14.1%)	2.16 (1.06-4.40)**
Negative Distress	466	26 (5.58%)	1.00

*Large confidence intervals due to quasi-complete separation

**Statistically Significant

Table 8: Multivariable logistic regression model on Validated Dataset of Factors Associated with Thoughts of Self-Harm

Characteristic	Adjusted Odds Ratio (95% CI)	P-value
Gender		
Female	0.40 (0.12-1.32)	0.13
Site		
Torrington	2.18 (0.78-6.12)	0.14
Guilford	0.17 (0.05-0.66)	0.01*
Depression scores		
Severe	8.23 (1.72-39.3)	0.01*
Moderately severe	3.72 (1.24-11.2)	0.02*
Cancer Type		
Prostate	7.55 (0.96-59.6)	0.06

*Statistically significant

List of Figures:

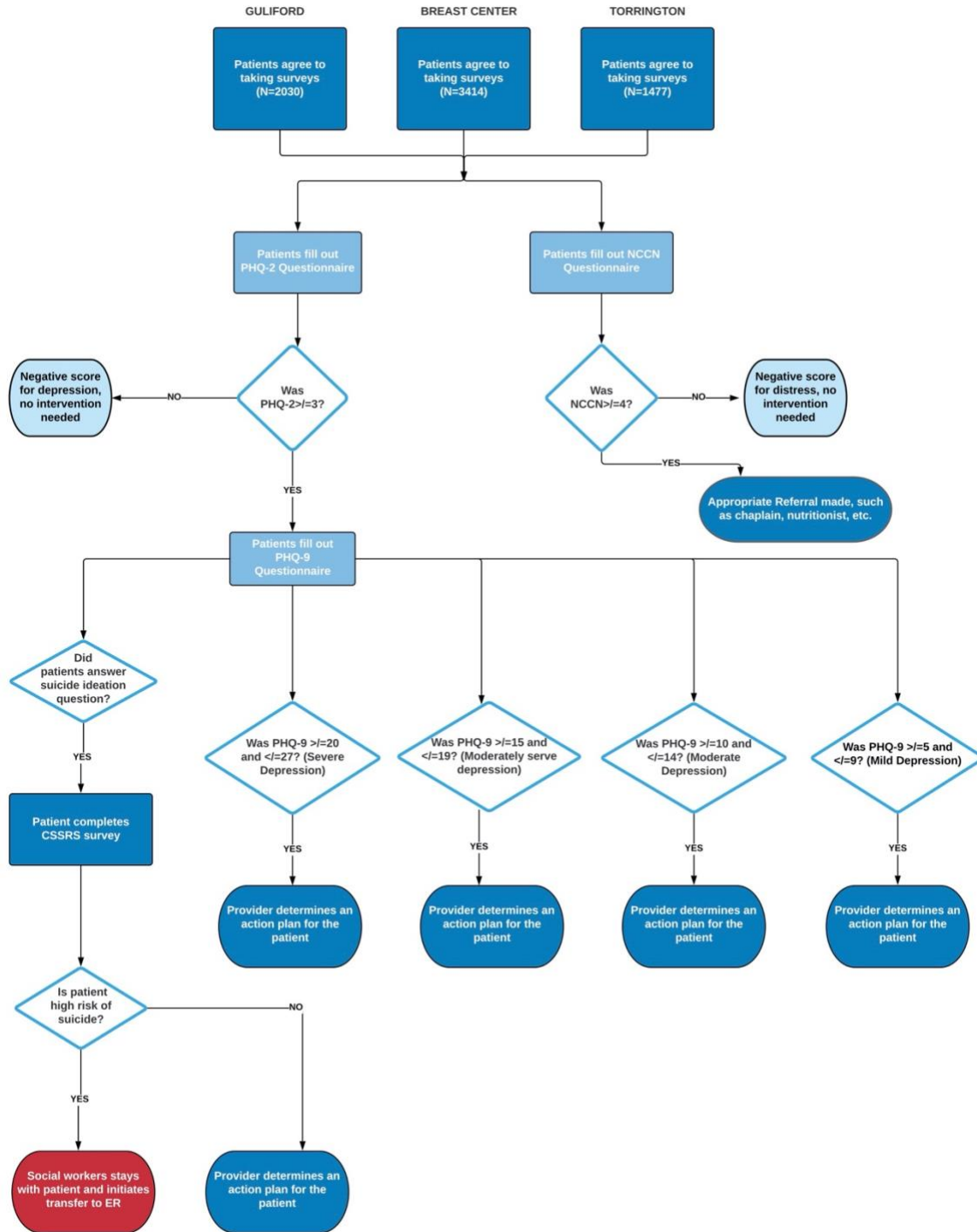


Figure One: Current Workflow for Electronic Depression and Distress Process

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